DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 8 2009

Re: Profender
Docket No.: FDA-2007-E-0228

The Honorable Jon Dudas
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,514,773, filed by Astellas Pharma Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Profender (emodepside, praziquantel), the animal drug product claimed by the patent.

The total length of the regulatory review period for Profender is 1,585 days. Of this time, 1,542 days occurred during the testing phase and 43 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 512(j) of the Federal Food, Drug, and Cosmetic Act involving this animal drug product became effective: February 27, 2003.

   The applicant claims June 2, 2000, as the date the investigational new animal drug application (INAD) became effective. However, the date that a major health or environmental effects test is begun or the date on which the agency acknowledges the filing of a notice of claimed investigational exemption for a new animal drug, whichever is earlier, is the effective date for the INAD. According to FDA records, February 27, 2003, is the effective date for the INAD.

2. The date the application was initially submitted with respect to the animal drug product under subsection 512(b) of the Federal Food, Drug, and Cosmetic Act: May 18, 2007.

   The applicant claims May 15, 2007, as the date the new animal drug application (NADA) for Profender (NADA 141-275) was initially submitted. However, a review of FDA records reveals that NADA 141-275 was initially submitted on May 18, 2007.

3. The date the application was approved: June 29, 2007.

FDA has verified the applicant's claim that NADA 141-275 was approved on June 29, 2007.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Steven G. Baxter
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